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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,150	07/25/2001	Gary R. DelDuca	47097-01080	6442

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EXAMINER

CHAWLA, JYOTI

ART UNIT PAPER NUMBER

1761

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/915,150

Applicant(s)

DELDUCA ET AL.

Examiner

Jyoti Chawla

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-37, 87-90 and 161-171 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-37, 87-90 and 161-171 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/30/06</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 30, 2006 has been entered.

Applicant's amendment filed on May 30, 2006 has been entered. Claims 1, 22 and 161 have been amended. Claims 1-37, 87-90, and 161-171 remain pending for examination.

### ***Claim Objections***

Claims 1, 22 and 161 are objected to because of the following informalities:

Claims 1, 22 and 161 recite (A method of manufacturing a modified atmosphere package, the method comprising the acts of), the language of the preamble consists of terms "the acts of" followed by a number of steps. The term "the acts of" does not affect the meaning of the claim and is considered redundant. For examination purposes, it will be understood that the term "the acts of" address "the steps of " that follow the preamble of claims 38, 119 and 138. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's arguments, with respect to "turns brown in natural time period" have been fully considered. Therefore, the 35 USC 112 second Paragraph Rejection of the term "turns brown in a natural time period" has been withdrawn.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-6,8-11,13-26,28-30,32-37,87-90,161,162,164-171 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carr et al. (US 6054153) in view of Woodruff et al. (US 4522835) and Koch et al. (US 3459117) and Shaklai (US 6042859).

See the reasons stated in the Office Action mailed January 25, 2006.

The amendment "meat having meat pigment" does not constitute a patentable difference in the claimed invention and the rejections in the office actions stated above still stand.

Claims 1,2,5-10,12-15,18-23,25-29,31-34,36,37,87-90,161-171 are rejected under 35 U.S.C. 103(a) as being unpatentable over Breen et al. (US 5711978) in view of

Woodruff et al. (US 4522835) and Koch et al. (US 3459117) and Shaklai (US 6042859) and Verbruggen (DE 1935566 A).

See the reasons stated in the Office Actions mailed January 25, 2006.

The amendment "meat having meat pigment" does not constitute a patentable difference in the claimed invention and the rejections in the office actions stated above still stand.

### ***Response to Arguments***

The 35 USC 112 second Paragraph Rejection of the term "turns brown in a natural time period" has been withdrawn.

Applicant's arguments filed May 30, 2006 have been fully considered but they are not persuasive. Applicant's declaration by one of the co-inventors Mr. Gary R. DelDuca ("Fifth Declaration of Gary R Delduca") to assist in showing the non-obviousness of the invention has been considered and found non persuasive.

(A) In response to applicant's argument that there is no motivation to combine the references used in the rejections made under 35 U.S.C. 103(a) (Remarks, III to IV B, Pages 23-25), the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

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In this case, Carr et al. (US 6054153) or Breen et al. (US 5711978), disclose a modified atmosphere package that is capable of holding raw meat in lower oxygen atmosphere to prevent metmyoglobin formation until it is ready to be exposed to oxygen rich air at a later time. The rejections do not rely on Shaklai and Koch et al. alone, but in combination with Woodruff et al., to provide the motivation for modifying Carr et al. or Breen et al. and including CO in the meat package. Woodruff et al., teach that CO concentrations in the recited range of the applicant have been known to provide good color in meat during its transportation and storage. Woodruff et al. are further relied on for the reason that it would be obvious to vary the amount of CO in the modified atmosphere based on the type of meat and the time period between exposures to a non-CO/non-O<sub>2</sub> atmosphere before the exposure to CO. Shaklai and Koch et al., teach that (1) The time it takes for a meat surface to brown after removal from storage with CO depends on the time the meat is exposed to CO and (2) CO associated with a meat's surface in a modified atmosphere package (i.e. such as the CO atmosphere taught by Woodruff et al.) is removably associated with the meat. Verbruggen provides further evidence of the conventionality of utilizing a carbon dioxide and carbon monoxide gas mixture for preserving meat.

Thus, Shaklai and Koch et al., provide evidence that the packages of either Carr et al. or Breen et al. modified by Woodruff et al., who teaches surface contact of a meat with CO to maintain a red color, will have CO removably associated with the meat in a natural time period (i.e. since only the surface is affected by the CO), depending on time it exposed to CO. Thus, the art of record does show that meat exposed to CO will brown

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within a natural period after removal of CO and exposure to normal atmosphere.

Therefore, not only is there motivation to combine the references, but also there is reasonable expectation of success in doing so.

(B) Applicants argue that individual references do not teach or suggest the invention (Remarks, IV B, Pages 24-25). In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicants argue that Woodruff et al., do not suggest that the use of CO turns meat brown in a natural time period, the applicants are reminded that Woodruff et al., teach addition of 0.1% to 3% of CO in a relatively inert atmosphere of CO<sub>2</sub> and N<sub>2</sub>, as recited by the applicant. Woodruff teaches that CO concentrations in the recited range of the applicant have been known to provide good color in pigmented meat during its transportation and storage. Woodruff et al., further teach that it would be obvious to vary the amount of CO in the modified atmosphere based on the type of meat and the time period between exposures to a non-CO/non-O<sub>2</sub> atmosphere before the exposure to CO.

Applicants further argue that Shaklai and Koch et al., do not suggest that the use of CO turns meat brown in a natural time period (Remarks, IV B, Pages 24-25). In response the applicants are reminded that Shaklai and Koch et al. are relied on as evidence to

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show that (1) The time it takes for a meat surface to brown after removal from storage with CO depends on the time the meat is exposed to CO and (2) CO associated with a meat's surface in a modified atmosphere package (i.e. such as the CO atmosphere taught by Woodruff et al.) is removably associated with the meat. Specifically, Shaklai, as stated in the previous office action, teaches the time it takes for a meat surface to brown after removal from storage with CO depends on the time the meat is stored with CO (e.g. in Examples 3 and 4). Koch et al., as stated in the previous office action, provide the evidence that contact with CO on the surface of meat for 7 days does not fix the meat color such that the meat does not remain red after 3 days when the CO-containing packaging is removed from the meat (Column 2, line 67 to Column 3, lines 5-16).

Applicants argue that Koch et al. only teach the primal cuts of meat (Remarks, IV B, Page 24), Koch et al., teach the use of their package for primal as well as the final cuts (column3, lines 4-17). The reference also teaches a bag (Figure 4, Column 3, 38-50) which is suitable for individual cuts and ground meat.

Shaklai and Koch et al., provide evidence that the packages of either Carr et al. or Breen et al. modified by Woodruff et al., who teaches surface contact of a meat with CO to maintain a red color, will have CO removably associated with the meat in a natural time period (i.e. since only the surface is affected by the CO), depending on the time the meat is exposed to CO. Verbruggen has been relied on as further evidence of the conventionality of utilizing a carbon dioxide and carbon monoxide gas mixture for preserving meat.



(C) Applicants state that CO has a greater affinity for hemoglobin than oxygen, and that Applicant's invention would not be expected to turn brown in a natural time period.

However, Koch et al., and Shaklai and Woodruff et al., teach that the meat that has been exposed to CO will turn red, but Koch and Shaklai teach that CO will not fix the meat color, as discussed above. Therefore, it would not be unexpected that meat exposed to CO in the modified atmospheric package (as disclosed in the invention), would turn brown in a natural time period upon removal of CO and exposure to O<sub>2</sub>.

(D) Regarding FDA, Sorheim, Whirlpool, and Dr. Hunt (Remarks, IV A, Pages 23-21), the applicant states that their teaching that CO "fixed" the color of the meat pigment was never addressed, the examiner wishes to remind the applicant that Woodruff et al., and Koch et al., provide evidence that CO is removably associated with a meat surface. As stated in the previously mailed Office Action, Koch et al. teach that the meat does not stay saleable red after 3 days after exposing a meat surface to CO for 7 days, i.e., discoloration or browning occurs in meat in a natural time period (3 days). Therefore, Koch et al. teach that CO does not fix the color of the meat and the meat does not remain a fixed red color after removal of CO and exposure to normal atmosphere. Also stated previously, Shaklai teaches that the time period, for which the meat remains red, depends on when the meat was exposed to the CO after slaughter, and the concentration of CO. Thus, the art of record does show that meat exposed to CO will

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brown within a natural period (Koch et al.) and is not fixed, depending on the level of CO and time exposed (Shaklai).

Regarding the FDA regulation, while CO was not allowed in meat storage since at least 1962 in the US, this is not relevant to the issue of obviousness in this case because Patent law is independent from FDA regulatory law. This issue often is discussed with respect to the determination of pharmaceutical utility (MPEP 2107.01: Section V): "FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws." *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995) (citing *Scott v. Finney*, 34 F.3d 1058, 1063, 32 USPQ2d 1115, 1120 (Fed. Cir. 1994)). Furthermore, it is noted that the US Patents cited in the Office action, such as *Woodruff*, illustrate that Patent law is independent from FDA regulatory law.

(E) Regarding the independent claims 1, 22 and 161, applicants argue that the evidence presented by Sorheim, Whirlpool and Dr. Hunt indicated that CO "fixed" the color of the meat pigment (Remarks, V, Pages 25-26). The applicants are respectfully reminded that *Woodruff et al.*, and *Shaklai et al.*, teach that the meat pigment is reversibly bound to CO and is not fixed as argued by the applicant (see above).

Therefore, the evidence submitted has been considered but is not persuasive and the obviousness rejections from above and previous office actions are maintained.

(F) In response to applicant's argument about the dependent claims 2-21, 23-37, 162-171 (Remarks, VI, Page 26), the examiner maintains the rejections from above and the previous office actions.

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(G) With respect to the present invention meeting a long-felt need, establishing long-felt need requires objective evidence that an art recognized problem existed in the art for a long period of time without solution. The relevance of long-felt need and the failure of others to the issue of obviousness depends on several factors. First, the need must have been a persistent one that was recognized by those of ordinary skill in the art. In *re* Gershon, 372 F.2d 535, 539, 152 USPQ 602, 605 (CCPA 1967). It is notoriously well known in the art, as discussed in the various references cited, that a red colored meat at the retail outlet is most desired. It was also known that meat exposed to CO in a modified atmosphere environment would provide the meat with a red color after the meat was removed from the modified atmosphere environment.

(H) With respect to the commercial success, it is not clear if the claimed invention resulted in the commercial success or whether other factors contributed to the success, such as increase advertising/marketing. " In considering evidence of commercial success, care should be taken to determine that the commercial success alleged is directly derived from the invention claimed, in a marketplace where the consumer is free to choose on the basis of objective principles, and that such success is not the result of heavy promotion or advertising, shift in advertising, consumption by purchasers normally tied to applicant or assignee, or other business events extraneous to the merits of the claimed invention, etc. "(*In re* Mageli, 470 F.2d 1380, 176 USPQ 305 (CCPA 1973)).

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In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-37 and 87-90 and 162-171 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-35, 81-109, and 148-155 of copending Application No.10/190,375. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim a method of making a modified atmosphere package with carbon monoxide. The application 10/190375 claims the carbon monoxide range of he present

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application (09/915150) claims carbon monoxide levels of not greater than 0.8% and 30.01-.8% (broadest range) by volume that include the ranges recited in the present application (i.e., 0.1 to 0.8%).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 2, 4-9, 11-13, 16-23, 25-32, 35-37, 88, 90, 161-167 and 171 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 38-40, 42, 44-56, 76-78, 80-86, 119-120, 124-140, 143-159, 162-168 of copending Application No. 09/965426. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims differ only in the amount of carbon monoxide utilized.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 2, 9-12, 16, 21-23, 29-31, 36-37, 161-162 and 165-166 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 70-75, 87-100 of copending Application No. 10/424, 460. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims differ only in the amount of carbon monoxide utilized.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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***Remarks/ Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jyoti Chawla whose telephone number is (571) 272-8212. The examiner can normally be reached on 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (571) 272-1398. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jyoti Chawla  
Examiner  
Art Unit 1761

  
**KEITH HENDRICKS**  
**PRIMARY EXAMINER**